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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/901,014	07/10/2001	Wei-Sing Chu	2313-116	8862

6449 7590 01/02/2009

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EXAMINER	
YANG, NELSON C	
ART UNIT	PAPER NUMBER
1641	

NOTIFICATION DATE	DELIVERY MODE
01/02/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	09/901,014	CHU, WEI-SING	
	Examiner	Art Unit	
	Nelson Yang	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *70,72-75,77-79,92-96 and 98-106* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *70,72-75,77-79,92-96 and 98-106* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 July 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application.
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 16, 2008 has been entered.

Response to Amendment

2. Applicant's amendment of claims 70 and 98 is acknowledged and has been entered.

3. Claims 70, 72-75, 77-79, 92-96, 98-106 are currently pending and under examination.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 70, 72-75, 77, 78, 92-96, 105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Northrup et al. [US 5,639,423] in view of Gravlee, Jr. [US 3,961,097], Ishibashi et al. [US 5,984,881], and Antich et al. [US 5,197,475].

With respect to claim 70, Northrup et al. teach ultrasonic Lamb-wave devices (abstract) comprising a reactor equipped with a Lamb-wave transducer connected to an inductor

(ultrasound transducer and generator) (column 7, lines 29-42) and a Lamb-wave sensor (first sensor) in a reaction chamber (column 7, lines 29-35), wherein the reaction chamber contains a Lamb-wave transducer that acts as an agitator, mixer, or sonochemical inducer (column 7, lines 28-35). Northrup et al. further teach temperature is monitored by measurement of the resistance of polycrystalline layers (column 9, lines 59-64), and also teach sensors for measuring density and viscosity (column 11, lines 40-48), as well as optical detection means (column 6, lines 36-52). Northrup et al. also teach a power source/control system (fig.1, column 6, lines 53-63) for controlling the reaction, either by inductive coupling, capacitive coupling, or by electromagnetic coupling. Detection signals may be processed and stored by integrated microelectronic devices so that result interpretation and control mechanisms can be integrally contained (column 4, lines 40-45). Nothrup et al. further disclose that the system may be used to process tissues (column 5, lines 58-60). Northrup et al. do not teach a solution in the reaction chamber for fixing a tissue sample, nor do Northrup et al. specifically teach a central processing unit that adjusts the frequency or intensity of the ultrasound energy in response to a signal received from the sensor.

Gravlee, Jr., however, teaches that a method for fixing and processing a tissue specimen comprising sequentially immersing the specimen in a fixing agent, a dehydrating agent, a clearing agent, and paraffin while applying ultrasonic energy to the specimen during each of the steps, wherein the specimen and processing agents are contained in a vessel (column 2, lines 1-10). The intensity of application of the energy is controlled during the fixing steps to ensure that cavitation does not occur within the bath (column 2, lines 12-15). Gravlee, Jr. further teaches that the application of ultrasonic energy agitates the agent in the vessel, thus reducing the time required to process the specimen (column 3, lines 42-48).

Therefore, one of ordinary skill in the art at the time of the invention in possession of the ultrasonic device of Northrup et al., when presented with the method disclosed by Gravlee, Jr., would have been motivated to include solutions for fixing a tissue sample in the reaction chamber, in order to reduce the total preparation time needed when fixing and impregnating a tissue specimen in paraffin.

Ishibashi et al. further disclose an ultrasonic therapeutic apparatus comprising a computer (column 25, lines 49-68), which would contain a central processing unit, which controls the power supply for driving the applicator for producing ultrasonic waves (column 25, lines 50-53), as well as an adjusting means feedback from an ultrasonic probe (column 4, lines 5-12 and column 40, lines 20-32). The adjusting means comprises a system controller which may measure and adjust the intensity of the ultrasound (column 16, lines 20-25) as well as include a safeguard (column 17, lines 30-37) to ensure that the ultrasound pulses are within an allowable range (column 19, lines 58-65)

Therefore, it would have been obvious to one of ordinary skill in the art to adapt the computer and adjusting means of Ishibashi et al. to the device of Northrup et al. for the purpose of performing the method of Gravlee, Jr., wherein the computer would be capable of adjusting the frequency and intensity of the ultrasound based on feedback from the ultrasound probe to ensure that the ultrasound is within an allowable range, in order to control the application of the ultrasound during the fixing steps to ensure that cavitation does not occur within the bath, as dictated by Gravlee, Jr., thus minimizing damage to the tissue without requiring manual intervention.

Furthermore, while Northrup et al. and Gravlee, Jr. teach that the ultrasonic transducers are located outside the chamber containing the solution and transmit ultrasonic energy into the chamber (see Gravlee, Jr., column 3, lines 32-48), Antich et al. disclose that transducers may be external to a container such as a bag and transmit ultrasound through the container, as done by Gravlee, Jr., or the transducer can be immersed in the container (column 8, lines 20-30), thus demonstrating that these two locations of the transducer are equivalent structures known in the art. Therefore, because these two locations for the transducers were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute placing the transducer in the container and immersed in the solution of Gravlee et al. for placing the transducer outside the container.

6. With respect to claims 72-74, Northrup et al. disclose that the density is measured (column 11, lines 45-47) by monitoring the wave characteristics (which would also allow for measurement of frequency of the ultrasound) using Lamb-wave sensors (column 11, lines 39-42), which are ultrasound sensors.

7. With respect to claim 75, Ishibashi et al. disclose that the computer is capable of processing received signals from the ultrasonic probe (column 25, lines 56-67).

8. With respect to claims 77 and 78, Northrup et al. disclose that the transducer is capable of producing Lamb waves with frequencies from 1 to 200 MHz (column 11, lines 3-10).

9. With respect to claim 92, Gravlee, Jr. teaches that the fixing agent may be 10% solution of formalin in water (column 3, lines 15-20).

10. With respect to claim 93, Gravlee, Jr. teaches that the dehydrating agent may be an alcohol (column 3, lines 23-25).

11. With respect to claim 94, Gravlee, Jr. teaches that the clearing agent may be xylene (column 3, lines 25-27).

12. With respect to claim 95, Gravlee, Jr. teaches that the tissue is impregnated with paraffin (column 3, lines 30-32).

13. With respect to claim 96, Northrup et al. teach pumps (LW_1, LW_2, LW_3) that pump solution into the reaction chamber and a pump that pumps solution out of the reaction chamber (LW_{DP}) and into the detection chamber (column 7, lines 35-37).

14. With respect to claims 105, Northrup et al. disclose that the transducer is further capable of producing Lamb waves with frequencies from 1 to 200 MHz (column 11, lines 3-10).

15. Claims 79, 98-104, 106 are rejected under 35 U.S.C. 103(a) as being unpatentable over Northrup et al. [US 5,639,423] in view of Gravlee, Jr. [US 3,961,097], Ishibashi et al. [US 5,984,881], and Antich et al. [US 5,197,475], as applied to claim 70 above, and further in view of Vago [US 5,665,141].

With respect to claim 79, Northrup et al. do not specifically teach that the transducer produces ultrasound of a power in the range of 0.01-200 W/cm^2.

Vago, however, teaches a power density of 0.1 to 5 W/cm^2 (column 3, lines 45-55), and further discloses that the frequency and intensity of the ultrasound should be selected to avoid tissue damaging heating effects (column 7, lines 60-67). Furthermore, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranged involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to ensure that the transducers of Northrup et al. are capable producing ultrasound of a power in the range of 0.1 to 5 W/cm^2 through normal optimization procedures known in the art, in order to avoid tissue-damaging heating effects.

16. With respect to claim 98, Northrup et al. teach the invention as disclosed above in claim 70. Northrup et al. do not specifically teach that the transducer produces ultrasound of a power in the range of 0.01-200 W/cm^2.

Vago, however, teaches a power density of 0.1 to 5 W/cm^2 (column 3, lines 45-55), and further discloses that the frequency and intensity of the ultrasound should be selected to avoid tissue-damaging heating effects (column 7, lines 60-67). Furthermore, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranged involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to ensure that the transducers of Northrup et al. are capable producing ultrasound of a power in the range of 0.01-200 W/cm^2 through normal optimization procedures known in the art, in order to avoid tissue-damaging heating effects.

17. With respect to claim 99, Northrup et al. disclose that the transducer is further capable of producing Lamb waves with frequencies from 1 to 200 MHz (column 11, lines 3-10).

18. With respect to claims 100-102, the density is measured (column 11, lines 45-47) by monitoring the wave characteristics (which would also allow for measurement of frequency) using Lamb-wave sensors (column 11, lines 39-42), which are ultrasound sensors.

19. With respect to claim 103, Ishibashi et al. disclose that the computer is capable of processing received signal from the ultrasonic probe (column 25, lines 56-67).

20. With respect to claim 104, Northrup et al. teach pumps ($(LW_1$, LW_2, $LW_3)$ that pump solution into the reaction chamber and a pump that pumps solution out of the reaction chamber (LW_{DP}) and into the detection chamber (column 7, lines 35-37).

21. With respect to claim 106, Northrup et al. disclose that the transducer is further capable of producing Lamb waves with frequencies from 1 to 200 MHz (column 11, lines 3-10).

Double Patenting

22. Claims 70, 72-74, 93-95, 98, 100-103 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 7,262,022. Although the conflicting claims are not identical, they are not patentably distinct from each other because the invention recited in the conflicting claims comprises a system for fixing a tissue sample comprising a reaction chamber containing a fixative, ethanol, xylene, or paraffin (claims 1, 4-7), an ultrasonic transducer (claim 1), a central processing unit coupled to the transducer (claim 1), and sensors for detecting temperature and ultrasound energy (claim 3). While the conflicting claims do not explicitly recite an ultrasound generator, they do discuss producing ultrasound energy, and therefore it would have been obvious to one of ordinary skill in the art to have provided an ultrasound generator to generate the ultrasound energy. The claims of the conflicting application further recite that the central processing unit would be able to process information from the sensors (claim 11).

Claims 70, 79, 98-99, 103, 105-106 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 92-108 of

copending Application No. 11/525,853 [US 2007/0072258]. Although the conflicting claims are not identical, they are not patentably distinct from each other because the invention recited in the conflicting claims comprises a system for fixing a tissue sample comprising a reaction chamber containing a fixative, ethanol, xylene, or paraffin (claims 92, 103-106), an ultrasonic transducer (claim 92) capable of applying ultrasound at 100 KHz to 50 MHz and 0.01 to 5 W/cm^2 (claim 102), a central processing unit coupled to the transducer (claim 92), and sensors (claim 94). While the conflicting claims do not explicitly recite an ultrasound generator, they produce ultrasound energy, and therefore it would have been obvious to one of ordinary skill in the art to have provided an ultrasound generator to generate the ultrasound energy.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

23. Applicant's arguments with respect to claims 70, 72-75, 77-79, 92-96, 98-106 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

24. No claims are allowed.

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571)272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

26. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nelson Yang/
Primary Examiner, Art Unit 1641